

902 KAR 2:020. Reportable disease surveillance.

RELATES TO: KRS 211.180(1), 214.010, 214.645, 333.130

STATUTORY AUTHORITY: KRS 194A.050, 211.090(3), 211.180(1), 214.010

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.180(1) requires the cabinet to implement a statewide program for the detection, prevention, and control of communicable diseases, chronic and degenerative diseases, dental diseases and abnormalities, occupational diseases and health hazards peculiar to industry, home accidents and health hazards, animal diseases which are transmissible to man, and other diseases and health hazards that may be controlled. KRS 214.010 requires every physician, advanced practice registered nurse, and every head of family to notify the local health department of the existence of diseases and conditions designated by administrative regulation of the cabinet. This administrative regulation establishes notification standards and specifies the diseases requiring immediate, urgent, priority, routine, or general notification, in order to facilitate rapid public health action to control diseases, and to permit an accurate assessment of the health status of the Commonwealth.

Section 1. Definitions. (1) "Authorize" means to confer rights to the Kentucky Department for Public Health in the NHSN database at the healthcare facility level.

(2) "Health facility" is defined by KRS 216B.015(13).

(3) "Health professional" means a professional licensed under KRS Chapters 311 through 314.

(4) "Healthcare-associated infection" or "HAI" means an infection acquired by a person while receiving treatment for a separate condition in a health care setting.

(5) "HIV case report" means an HIV infection or AIDS diagnosis which:

(a) Has been confirmed by laboratory test results; or

(b) Meets the definition of AIDS established within the Centers for Disease Control and Prevention (CDC) guidelines.

(6) "Kentucky Department for Public Health Advisory" means a notification to health professionals, health facilities, and laboratories subject to this administrative regulation identifying a new health threat that warrants reporting through the procedures of this administrative regulation.

(7) "Medical laboratory" is defined by KRS 333.020(3).

(8) "National Healthcare Safety Network" or "NHSN" means the nation's most widely used healthcare-associated infection (HAI) tracking system as provided to medical facilities by the Centers for Disease Control and Prevention.

(9) "National reference laboratory" means a laboratory located outside of Kentucky which has been contracted by a Kentucky health professional, laboratory, or healthcare facility to provide laboratory testing.

(10) "Outbreak" means:

(a) Two (2) or more cases, including HAIs, that are epidemiologically linked or connected by person, place, or time; or

(b) A single case of an HAI not commonly diagnosed.

(11) "Pharmacist" means a professional licensed under KRS 315.010.

(12) "Select agent" means a biological agent or toxin that could pose a severe threat to public health, plant health, animal product, or plant product as determined by the National Select Agent Registry (NSAR) at www.selectagents.gov.

(13) "Veterinarian" means a professional licensed under KRS 321.181.

Section 2. Notification Standards. (1) Health Professionals and Facilities. A health profes-

sional and a health facility shall give notification if:

(a) The health professional makes a probable diagnosis of a disease specified in Section 3, 5, 6, 7, 8, 10, 13, 14, 15, or 16 of this administrative regulation; and

(b) The diagnosis is supported by:

1.a. Clinical or laboratory criteria; and

b. Case classifications published by the Centers for Disease Control and Prevention at wwwn.cdc.gov/nndss; or

2. A health professional's medical opinion that the disease is present.

(2) A single report by a health facility of a condition diagnosed by a test result from the health facility's laboratory shall constitute notification on behalf of the health facility and its laboratory.

(3) A health facility may designate an individual to report on behalf of the health facility's laboratory, pharmacy, and the health facility's other clinical entities.

(4) Notification shall be given to the local health department serving the jurisdiction in which the patient resides.

(5) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(6) The reporting health professional shall furnish:

(a) Information required in Section 4(16) of this administrative regulation; and

(b) Clinical, epidemiologic, and laboratory information pertinent to the disease including sources of specimens submitted for laboratory testing.

(7) Medical Laboratories. Upon a laboratory test result which indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in Section 3, 5, 6, 7, 8, 10, 13, 14, 15, or 16 of this administrative regulation, the laboratory shall report the result to the local health department serving the county in which the patient resides.

(8) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(9) The reporting laboratory shall furnish the information required in Section 4(16) of this administrative regulation.

(10) National Reference Laboratories. Upon a test result performed by a national reference laboratory which indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in Section 3, 5, 6, 7, 8, 10, 13, 14, 15, or 16 of this administrative regulation, the director of a medical laboratory, a health facility, or the health professional that referred the test to the national reference laboratory shall ensure that the result is reported by the national reference laboratory to the local health department serving the jurisdiction in which the patient resides.

(11) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(12) The report shall include the information required by Section 4(16) of this administrative regulation.

Section 3. Submission of Specimens to the Kentucky Department for Public Health Division of Laboratory Services. (1) A medical laboratory and a national reference laboratory in receipt of diagnostic specimens originating from the Commonwealth of Kentucky shall send specimens or clinical isolates for diseases outlined in subsection (5) of this section to the Division of Laboratory Services for primary or confirmatory testing and related studies.

(2) A medical laboratory or national reference laboratory using non-culture techniques to identify bacterial agents of diarrheal disease, such as enzyme immunoassays (EIAs) or molecular assays, shall attempt isolation of the etiologic agent identified. Clinical isolates shall be

submitted to the Division of Laboratory Services.

(3) If the culture attempts do not produce a clinical isolate, the direct specimen, submitted in the appropriate preservative, shall be sent to the Division of Laboratory Services. A submitting laboratory shall provide the name of the etiologic agent detected by the non-culture technique at the time of specimen submission.

(4) A medical laboratory performing this test shall continue to follow the state's requirement for the submission of appropriate materials to the state public health laboratory.

(5) A medical or national reference laboratory shall submit clinical isolates or, if not available, the direct specimen from the following diseases to the Division of Laboratory Services:

- (a) Botulism;
- (b) Brucellosis;
- (c) Campylobacteriosis;
- (d) Cholera and diseases caused by other *Vibrio* species;
- (e) Diphtheria;
- (f) *Escherichia coli* O157:H7;
- (g) Hemolytic Uremic Syndrome (HUS) – Post Diarrheal;
- (h) Listeriosis;
- (i) Measles;
- (j) Meningococcal infections;
- (k) Rabies animal;
- (l) Rubella;
- (m) Salmonellosis;
- (n) Shiga toxin-producing *E. coli* (STEC);
- (o) Shigellosis;
- (p) Tuberculosis;
- (q) Tularemia; and
- (r) Typhoid fever.

Section 4. Reporting Classifications and Methods. (1) Immediate reporting. A report required by Section 10(1) and (2) of this administrative regulation to be made immediately shall be:

(a) Made by telephone to the local health department serving the county in which the patient resides; and

(b) Followed up by electronic or fax submission to the local health department serving the county in which the patient resides within one (1) business day.

(2) Upon receipt of a report for a disease requiring immediate reporting, the local health department shall:

(a) Notify the Kentucky Department for Public Health by telephone; and

(b) Assist the department in carrying out a public health response.

(3) Weekend, evening, or holiday immediate notification. If local health department personnel cannot be contacted directly, notification shall be made by telephone using an emergency number provided by the local health department or the Kentucky Department for Public Health.

(4) For the protection of patient confidentiality, a report using the emergency number shall include:

(a) The name of the condition being reported; and

(b) A telephone number that can be used by the department to contact the reporting health professional or health facility.

(5) Urgent Reporting. A report made within twenty-four (24) hours as required by Section 5 of this administrative regulation shall be:

(a) Submitted electronically, by fax, or by telephone to the local health department serving

the county in which the patient resides; and

(b) If submitted by telephone, followed up by electronic or fax submission to the local health department serving the county in which the patient resides within one (1) business day.

(6) Upon receipt of a report for a disease requiring urgent reporting, the local health department shall:

(a) Notify the Kentucky Department for Public Health; and

(b) Assist the department in carrying out a public health response.

(7) Weekend, evening, or holiday urgent notification. If local health department personnel cannot be contacted directly, notification shall be made by telephone using an emergency number provided by the local health department or the Kentucky Department for Public Health.

(8) For the protection of patient confidentiality, notification using the emergency number shall include:

(a) The name of the condition being reported; and

(b) A telephone number that can be used by the department to contact the reporting health professional or health facility.

(9) Priority Reporting. A report made within one (1) business day as required by Sections 6, 14(4), and 15 of this administrative regulation shall be:

(a) Submitted electronically, by fax, or by telephone to the local health department serving the county in which the patient resides; and

(b) If submitted by telephone, followed up by electronic or fax submission of a report to the local health department serving the county in which the patient resides within one (1) business day.

(10) Upon receipt of a report for a disease requiring priority reporting, a local health department shall:

(a) Investigate the report and carry out public health protection measures; and

(b) Notify the Kentucky Department for Public Health of the case by electronic or fax submission within one (1) business day.

(11) The reporting health department may seek assistance in carrying out public health measures from the Kentucky Department for Public Health.

(12) Routine Reporting. A report made within five (5) business days, as required by Sections 7, 8, 9, 11(1), 13, 14(7), and 17 of this administrative regulation, shall be made electronically, by fax, or by mail to the local health department serving the county in which the patient resides.

(13) Upon receipt of a report of a disease or condition requiring routine reporting, a local health department shall:

(a) Make a record of the report;

(b) Answer inquiries or render assistance regarding the report if requested by the reporting entity; and

(c) Forward the report to the Kentucky Department for Public Health by electronic or fax submission of a report, or in writing within five (5) business days.

(14) General Reporting. A report made within three (3) months, as required by Section 16 of this administrative regulation, shall be made electronically, by fax, or by mail.

(15) A report submitted by fax or by mail shall be made using one (1) of the following reporting forms:

(a) EPID 200, Kentucky Reportable Disease Form;

(b) EPID 250, Kentucky Reportable MDRO Form, until electronic reporting is available pursuant to Section 9(1) of this administrative regulation;

(c) EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant Women or Child (aged five (5) years or less);

- (d) EPID 399, Perinatal Hepatitis B Prevention Form for Infants;
- (e) Adult HIV/AIDS Confidential Case Report form; or
- (f) Pediatric HIV/AIDS Confidential Case Report form.

(16) Information to be reported. Except as provided in subsections (3) and (7) of this section, a report required by this administrative regulation shall include:

- (a) Patient name;
- (b) Date of birth;
- (c) Gender;
- (d) Race;
- (e) Ethnicity;
- (f) Patient address;
- (g) County of residence;
- (h) Patient telephone number;
- (i) Name of the reporting medical provider or facility;
- (j) Address of the reporting medical provider or facility; and
- (k) Telephone number of the reporting medical provider or facility.

(17) A reporting health professional shall furnish the information listed in subsection (16) of this section and Section 2(6)(b) of this administrative regulation.

Section 5. Notifiable Infectious Conditions Requiring Urgent Notification. Notification of the following diseases shall be considered urgent and shall be made within twenty-four (24) hours:

- (1) Anthrax;
- (2) Botulism;
- (3) Brucellosis (multiple cases, temporally or spatially clustered);
- (4) Diphtheria;
- (5) Hepatitis A, acute;
- (6) Measles;
- (7) Meningococcal infections;
- (8) Novel influenza A virus infections;
- (9) Plague;
- (10) Poliomyelitis;
- (11) Rabies, animal;
- (12) Rabies, human;
- (13) Rubella;
- (14) Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV) disease;
- (15) Smallpox;
- (16) Tularemia;
- (17) Varicella;
- (18) Viral hemorrhagic fevers due to:
 - (a) Crimean-Congo Hemorrhagic Fever virus;
 - (b) Ebola virus;
 - (c) Lassa virus;
 - (d) Lujo virus;
 - (e) Marburg virus; or
 - (f) New world arenaviruses including:
 - 1. Guanarito virus;
 - 2. Junin virus;
 - 3. Machupo virus; and
 - 4. Sabia virus; and

(19) Yellow fever.

Section 6. Notifiable Infectious Conditions and Notifiable Non-Infectious Conditions Requiring Priority Notification. Notification of the following diseases or conditions shall be considered priority and shall be made within one (1) business day:

- (1) Arboviral diseases, neuroinvasive and non-neuroinvasive, including:
 - (a) California serogroup virus diseases, including diseases caused by:
 1. California encephalitis virus;
 2. Jamestown Canyon virus;
 3. Keystone virus;
 4. La Crosse virus;
 5. Snowshoe hare virus; and
 6. Trivittatus viruses;
 - (b) Chikungunya virus disease;
 - (c) Eastern equine encephalitis virus disease;
 - (d) Powassan virus disease;
 - (e) St. Louis encephalitis virus disease;
 - (f) Venezuelan equine encephalitis disease;
 - (g) West Nile virus disease;
 - (h) Western equine encephalitis virus disease; and
 - (i) Zika virus disease or infection or the birth of a child to a mother who was Zika-positive or Zika-inconclusive during any stage of pregnancy or during the periconceptional period;
- (2) Brucellosis (cases not temporally or spatially clustered);
- (3) Campylobacteriosis;
- (4) Carbon monoxide poisoning;
- (5) Cholera;
- (6) Cryptosporidiosis;
- (7) Dengue virus infections;
- (8) Escherichia coli O157:H7;
- (9) Foodborne disease outbreak;
- (10) Haemophilus influenzae invasive disease;
- (11) Hansen's disease (leprosy);
- (12) Hantavirus infection, non-Hantavirus pulmonary syndrome;
- (13) Hantavirus pulmonary syndrome (HPS);
- (14) Hemolytic uremic syndrome (HUS), post-diarrheal;
- (15) Hepatitis B, acute;
- (16) Hepatitis B infection in a pregnant woman;
- (17) Hepatitis B infection in an infant or a child aged five (5) years or less;
- (18) Newborns born to Hepatitis B positive mothers at the time of delivery;
- (19) Influenza-associated mortality;
- (20) Leptospirosis;
- (21) Listeriosis;
- (22) Mumps;
- (23) Norovirus outbreak;
- (24) Pertussis;
- (25) Pesticide-related illness, acute;
- (26) Psittacosis;
- (27) Q fever;
- (28) Rubella, congenital syndrome;

- (29) Salmonellosis;
- (30) Shiga toxin-producing E. coli (STEC);
- (31) Shigellosis;
- (32) Streptococcal toxic-shock syndrome;
- (33) Streptococcus pneumoniae, invasive disease;
- (34) Tetanus;
- (35) Toxic-shock syndrome (other than Streptococcal);
- (36) Tuberculosis;
- (37) Typhoid fever;
- (38) Vibriosis; and
- (39) Waterborne disease outbreak.

Section 7. Notifiable Infectious Conditions and Notifiable Non-Infectious Conditions Requiring Routine Notification. Notification of the following diseases shall be considered routine and shall be made within five (5) business days:

- (1) Babesiosis;
- (2) Coccidioidomycosis;
- (3) Creutzfeldt-Jakob disease;
- (4) Ehrlichiosis/Anaplasmosis;
- (5) Hepatitis C, acute;
- (6) Hepatitis C infection in a pregnant woman;
- (7) Hepatitis C infection in an infant or a child aged five (5) years or less;
- (8) Newborns born to Hepatitis C positive mothers at the time of delivery;
- (9) Histoplasmosis;
- (10) Lead poisoning;
- (11) Legionellosis;
- (12) Lyme Disease;
- (13) Malaria;
- (14) Spotted Fever Rickettsiosis (Rocky Mountain Spotted Fever);
- (15) Toxoplasmosis; and
- (16) Trichinellosis (Trichinosis).

Section 8. Notifiable Infectious Conditions Requiring Routine Notification by Electronic Laboratory Reporting. (1) Beginning October 1, 2016, notification of the following diseases shall be considered routine and shall be electronically reported to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within five (5) business days:

- (a) Cyclosporiasis;
- (b) Giardiasis;
- (c) Hepatitis B laboratory test results whether reported as positive or negative:
 - 1. Include the serum bilirubin levels taken within ten (10) days of the test of a patient who has tested positive; or
 - 2. Include the serum alanine aminotransferase levels taken within ten (10) days of the test of a patient who tested positive;
- (d) Hepatitis C laboratory test results whether reported as positive or negative:
 - 1. Include the serum bilirubin levels taken within ten (10) days of the test of a patient who has tested positive; or
 - 2. Include the serum alanine aminotransferase levels taken within ten (10) days of the test of a patient who tested positive; and
- (e) Varicella laboratory test results reported as positive for:

1. Isolation of varicella virus from a clinical specimen;
2. Varicella antigen detected by direct fluorescent antibody test;
3. Varicella-specific nucleic acid detected by polymerase chain reaction (PCR); or
4. A significant rise in serum anti-varicella immunoglobulin G (IgG) antibody level by a standard serologic assay.

(2) Reports made pursuant to this section shall include a diagnosis.

Section 9. Multi-Drug Resistant Organisms and Other Organisms Requiring Routine Notification by Electronic Laboratory Reporting. (1) Beginning October 1, 2016, notification of the following diseases shall be considered routine and shall be electronically reported to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within five (5) business days:

(a) Vancomycin-intermediate *Staphylococcus aureus* (VISA), which includes *S. aureus* cultured from any specimen that the results show a minimum inhibitory concentration (MIC) of 4-8 µg/mL per standard laboratory methods;

(b) Vancomycin-resistant *Staphylococcus aureus* (VRSA), which includes *S. aureus* cultured from any specimen that the results show a minimum inhibitory concentration (MIC) of greater than or equal to 16 µg/mL per standard laboratory methods;

(c) Methicillin-resistant *Staphylococcus aureus* (MRSA), which includes *S. aureus* cultured from any specimen that tests oxacillin-resistant, ceftazidime-resistant, or methicillin-resistant by standard susceptibility testing methods, or by a laboratory test that is FDA-approved for MRSA detection from isolated colonies. These methods may also include a positive result by any FDA-approved test for MRSA detection;

(d) Vancomycin-resistant *Enterococcus* species (VRE), only those identified to the species level, that are resistant to Vancomycin by standard susceptibility testing methods or by results from any FDA-approved test for VRE detection from specific specimen sources;

(e) *Clostridium difficile* (*C. difficile*) identified from a positive laboratory test result for a *C. difficile* toxin A or B (includes molecular assays {PCR} or toxin assays) or a toxin-producing organism detected by culture or other laboratory means performed on a stool sample;

(f) Carbapenem-resistant *Enterobacteriaceae* (CRE), which includes *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, or *Enterobacter* species testing resistant to imipenem, meropenem, doripenem, or ertapenem by standard susceptibility testing methods or by production of carbapenemase by an isolate demonstrated by using a recognized test;

(g) Cephalosporin-resistant *Klebsiella*, which includes *Klebsiella oxytoca*, *Klebsiella pneumoniae*, or a *Klebsiella* species testing non-susceptible (resistant or intermediate) to ceftazidime, cefotaxime, ceftriaxone, or cefepime;

(h) Extended-spectrum beta-lactamase Gram negative organisms (ESBL) *Enterobacteriaceae* species non-susceptible (resistant or intermediate) to ceftazidime, cefepime, ceftriaxone, or cefotaxime;

(i) Multidrug-resistant – *Acinetobacter* - Non-susceptibility (resistant or intermediate) to at least one (1) agent in at least three (3) antimicrobial classes of the following six (6) classes:

1. Ampicillin-sulbactam;
2. Cephalosporins (cefepime, ceftazidime);
3. β-lactam-β-lactamase inhibitor combination (piperacillin, piperacillin-tazobactam);
4. Carbapenems (imipenem, meropenem, doripenem);
5. Fluoroquinolones (ciprofloxacin or levofloxacin); and
6. Aminoglycosides (gentamicin, tobramycin, or amikacin); and

(j) Multidrug-resistant *Pseudomonas* - Non-susceptibility, resistant or intermediate, to at least one (1) agent in at least three (3) antimicrobial classes of the following five (5) classes:

1. Cephalosporins (cefepime, ceftazidime);
 2. β -lactam- β -lactam β -lactamase inhibitor combination (piperacillin, piperacillin-tazobactam);
 3. Carbapenems (imipenem, meropenem, doripenem);
 4. Fluoroquinolones (ciprofloxacin or levofloxacin); and
 5. Aminoglycosides (gentamicin, tobramycin, or amikacin).
- (2) The report of an organism under this section shall include the following:
- (a) Date of specimen collection;
 - (b) Source of specimen;
 - (c) Susceptibility pattern; and
 - (d) Name of the ordering health professional.
- (3) Upon a test result performed by a medical laboratory which indicates infection with an agent associated with one (1) or more of the diseases or conditions or a multi-drug resistant organism specified in this section, the director of the medical laboratory shall electronically report the result to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within five (5) days.
- (4) The report shall include a diagnosis.

Section 10. Newly Recognized Infectious Agents, HAI Outbreaks, Emerging Pathogens, and Pathogens of Public Health Importance. (1) The following shall be reported immediately by telephone to the Kentucky Department for Public Health:

- (a) A suspected incidence of bioterrorism caused by a biological agent;
 - (b) Submission of a specimen to the Kentucky Division of Laboratory Services for select agent identification or select agent confirmation testing; or
 - (c) An outbreak of a disease or condition that resulted in multiple hospitalizations or death.
- (2) An unexpected pattern of cases, suspected cases, or deaths which may indicate the following shall be reported immediately by telephone to the local health department in the county where the health professional is practicing or where the facility is located:
- (a) A newly-recognized infectious agent;
 - (b) An outbreak;
 - (c) An emerging pathogen which may pose a danger to the health of the public;
 - (d) An epidemic; or
 - (e) A non-infectious chemical, biological, or radiological agent.
- (3) A report of the following shall be considered priority and shall be reported to the local health department in the county where the health professional is practicing or where the facility is located within one (1) business day:
- (a) Suspected Staphylococcal or other foodborne intoxication; or
 - (b) Salmonellosis or other foodborne or waterborne infection.
- (4) The local health department shall:
- (a) Investigate the outbreak or occurrence;
 - (b) Carry out public health protection measures to address the disease or condition involved; and
 - (c) Make medical and environmental recommendations to prevent future similar outbreaks or occurrences.
- (5) The local health department may seek assistance from the Kentucky Department for Public Health.

Section 11. Laboratory Surveillance. (1) Medical or national reference laboratory results for the following shall be considered routine:

- (a) Influenza virus isolates;
- (b) PCR-positive test results for influenza virus; and
- (c) DNA molecular assays for influenza virus.

(2) The report shall include specific laboratory information pertinent to the result.

(3) Upon request by the Kentucky Department for Public Health, a health facility laboratory or a medical laboratory shall report the number of clinical isolates and information regarding the antimicrobial resistance patterns of the clinical isolates at intervals no less frequently than three (3) months for the following:

- (a) *Staphylococcus aureus*;
- (b) *Enterococcus* species; or
- (c) An organism specified in a request that includes a justification of its public health importance.

Section 12. Healthcare-Associated Infection Surveillance. (1) A healthcare facility in Kentucky that participates in CMS reporting programs shall authorize the CDC to allow the Kentucky Department for Public Health to access health care-associated infection data reported to NHSN.

(2) The Kentucky Department for Public Health shall preserve patient confidentiality and shall not disclose to the public any patient-level data obtained from any health care facility.

(3) The Kentucky Department for Public Health may issue reports to the public regarding healthcare-associated infections in aggregate data form which:

- (a) May identify individual health care facilities; and
- (b) Shall comply with methodology developed by the CDC and CMS for national reporting of health care-associated infections.

(4) The Kentucky Department for Public Health may evaluate healthcare-associated infection data for accuracy and completeness.

Section 13. Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) Surveillance. (1) A report of an HIV infection or AIDS diagnosis shall be considered routine and shall be reported within five (5) business days of diagnosis on one (1) of the following forms:

- (a) Adult HIV/AIDS Confidential Case Report form; or
 - (b) Pediatric HIV/AIDS Confidential Case Report form.
- (2) Health professionals and medical laboratories shall report:

(a) A positive test result for HIV infection including a result from:

1. 3rd generation immunoassay;
2. 4th generation immunoassay;
3. Western Blot;
4. PCR;
5. HIV-1 or HIV-2 differentiating such as Multispot;
6. HIV antigen;
7. HIV antibody;
8. CD4+ assay including absolute CD4+ cell counts and CD4+%;
9. HIV Viral Load Assay including detectable and undetectable values; or
10. A positive confirmatory serologic test result for HIV infection; or

(b) A diagnosis of AIDS that meets the definition of AIDS established within the CDC guidelines.

(3) A case report for a resident of Jefferson, Henry, Oldham, Bullitt, Shelby, Spencer, or Trimble County shall be submitted to the HIV/AIDS Surveillance Program of the Louisville-

Metro Health Department.

(4) A case report for a resident of the remaining Kentucky counties shall be submitted to the HIV/AIDS Surveillance Program of the Kentucky Department for Public Health, Division of Epidemiology and Health Planning.

(5) A case report for a person with an HIV infection without a diagnosis of AIDS shall include the following information:

- (a) The patient's full name;
- (b) The patient's complete address;
- (c) Date of birth using the format MMDDYYYY;
- (d) Gender;
- (e) Race;
- (f) Ethnicity;
- (g) Risk factor as identified by CDC;
- (h) County of residence;
- (i) Name of provider and facility submitting report including contact information;
- (j) Specimen collected;
- (k) Date and type of HIV test performed using the format MMDDYYYY;
- (l) Results of CD4+ cell counts and CD4+%;
- (m) Results of viral load testing;
- (n) Results of PCR, HIV culture, HIV antigen, and HIV antibody, if performed;
- (o) Results of TB testing, if available; and
- (p) HIV status of the person's partner, spouse, or children, as applicable.

(6) A reports of an AIDS case shall include:

- (a) Information in subsections (2) through (5) of this section;
- (b) Opportunistic infections diagnosed; and
- (c) Date of onset of illness.

(7) A report of AIDS shall be made whether or not the patient has been previously reported as having an HIV infection.

(8) If the patient has not been previously reported as having an HIV infection, the AIDS report shall also serve as the report of HIV infection as required by subsection (2) through (5) of this section.

Section 14. Sexually Transmitted Disease (STD). (1) Notification of a probable diagnosis of an STD as specified in subsection (4) or (7) of this section shall be made.

(2) The report shall provide the following information:

- (a) Pregnancy status; and
- (b) Clinical, epidemiologic, laboratory, and treatment information pertinent to the disease.

(3) Upon a laboratory test result which indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in subsection (4) and (7) of this section, a medical laboratory shall report to the Kentucky Department for Public Health information required by Section 4(16) of this administrative regulation.

(4) Sexually Transmitted Diseases Requiring Priority Notification. A report of the following shall be considered priority and shall be made within one (1) business day:

- (a) Congenital syphilis; or
- (b) Syphilis - primary, secondary, or early latent.

(5) Upon receipt of a report for a disease or condition specified in subsection (4) of this section, a local health department shall:

- (a) Investigate the report;
- (b) Carry out public health protection measures to address the disease or condition; and

(c) Forward the report to the Kentucky Department for Public Health within one (1) business day.

(6) The local health department may seek assistance from the Kentucky Department for Public Health.

(7) Sexually Transmitted Diseases Requiring Routine Notification. A report of the following shall be considered routine and shall be made within five (5) business days:

- (a) Chancroid;
- (b) Chlamydia trachomatis infection;
- (c) Gonorrhea;
- (d) Granuloma inguinale;
- (e) Lymphogranuloma venereum; or
- (f) Syphilis, other than primary, secondary, early latent, or congenital.

(8) Upon receipt of a report for a disease or condition specified in subsection (7) of this section, a local health department shall:

- (a) Make a record of the report using Form EPID 200, Kentucky Reportable Disease Form;
- (b) Forward the report to the Kentucky Department for Public Health within five (5) business days; and
- (c) Render assistance if requested by the reporting entity or the Kentucky Department for Public Health.

Section 15. Tuberculosis. (1) A pharmacist shall give notice if two (2) or more of the following medications used for the initial treatment of active tuberculosis are dispensed to an inpatient in a health facility or to an ambulatory patient in a health facility or a pharmacy:

- (a) Rifampin or rifabutin;
- (b) Isoniazid;
- (c) Pyrazinamide; and
- (d) Ethambutol.

(2) A report of tuberculosis shall be considered priority and shall be reported to the local health department serving the county in which the patient resides.

(3) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(4) The report shall include:

- (a) Information required in Section 4(16) of this administrative regulation; and
- (b) Names of the medications dispensed.

Section 16. Asbestosis, Coal Worker's Pneumoconiosis, and Silicosis. (1) A health professional shall report a diagnosis of the following to the Kentucky Department for Public Health within three (3) months of diagnosis:

- (a) Asbestosis;
- (b) Coal worker's pneumoconiosis; or
- (c) Silicosis.

(2) A report required under this section shall include the following information regarding the patient:

- (a) Name;
- (b) Address;
- (c) Date of birth; and
- (d) County of residence.

Section 17. Reporting of Communicable Diseases in Animals. (1) A diagnosis in an animal

of a condition known to be communicable to humans, except for rabies, shall require routine notification.

(2) A veterinarian shall report the diagnosis within five (5) business days to the local health department serving the county in which the animal is located.

(3) If a laboratory test indicates infection of an animal with an agent associated with a condition known to be communicable to humans, the director of a medical laboratory shall report the result to the local health department serving the county in which the animal is located within five (5) business days.

(4) The local health department receiving the report shall:

(a) Investigate the report;

(b) Carry out public health protection measures for the control of communicable diseases; and

(c) Forward the report to the Kentucky Department for Public Health within five (5) business days.

(5) The local health department may seek assistance from the Kentucky Department for Public Health.

Section 18. Kentucky Department for Public Health Advisory. (1) If the Secretary of the Cabinet for Health and Family Services or the Commissioner of the Department for Public Health determines that a disease not presently listed in this administrative regulation requires reporting, the secretary or commissioner may issue a Kentucky Public Health Advisory.

(2) The Kentucky Public Health Advisory shall include:

(a) Date and time the advisory is issued;

(b) A unique number to identify the advisory;

(c) Names for the disease or condition;

(d) A description of the disease or condition;

(e) Recommendations for health professionals, health facilities, and laboratories; and

(f) Notification requirements including:

1. The notification time interval;

2. Methods for notification; and

3. Forms to be completed and submitted with the notification.

(3) The duty to report by health professionals, health facilities, and laboratories pursuant to a Kentucky Public Health Advisory shall begin upon receipt of the advisory and shall remain in effect until the advisory is rescinded by order of the secretary or the commissioner.

Section 19. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) Form "EPID 200, Kentucky Reportable Disease Form", 6/2016;

(b) Form "EPID 250, Kentucky Reportable MDRO Form", 6/2014;

(c) Form "EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant Women or Child (aged five years or less)", 9/2016;

(d) Form "EPID 399, Perinatal Hepatitis B Prevention Form for Infants", 4/2012;

(e) Form "Adult HIV Confidential Case Report Form", 3/2013; and

(f) Form "Pediatric HIV Confidential Case Report Form", 3/2013.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. (CDS-2; 1 Ky.R. 187; eff. 12-11-1974; Am. 2 Ky.R. 464; eff. 4-14-1976; 11 Ky.R. 1518; 1786; eff. 6-4-1985; 16 Ky.R. 663; 1185; eff. 11-29-1989; 21 Ky.R. 128; eff. 8-17-1994; 23 Ky.R. 3119; 3597; 4131; eff. 6-16-1997; 27 Ky.R. 1099; 1489; eff. 12-

21-2000; 29 Ky.R. 812; 1273; eff. 10-16-2002; 31 Ky.R. 873; eff. 1-4-2005; 41 Ky.R. 1213; 1674; eff. 2-26-2015; 43 Ky.R. 122, 568; eff, 11-16-2016.)